REMARKS

Claim Amendments , 101, and 112 Claim Rejections

Claim 1 has been amended to recite a substantially planar restrictive member configured for implantation into a stomach of an animal, the restrictive member having an exterior perimeter adapted to contact inner walls of the stomach, and the restrictive member having an outer diameter between 7 and 20 centimeters.

Claims 1 and 12 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory stomach as it positively recites the stomach as a part of the invention. These claims have been amended to correct this.

Claims 1, 15, 19, and 20 have been rejected under 35 U.S.C. 112 for minor informalities. These claims have been amended to correct these errors.

The Examiner has also rendered claim 15 as indefinite since he states that the "staple retaining device" is not part of the gastrointestinal implant, but is part of the implantation tool. The spring clip retaining device can be part of the anchor. Support for this can be found in specification on page 6, lines 13-25. Thus, Applicant respectfully requests the Examiner to withdraw these rejections.

102(b) Rejections

Claims 1-2, 5-10, 12, 13, and 17-20 have been rejected under 35 U.S.C. 102(e) as being anticipated by Stack et al. (US 7,152,607). Claims 1, 2, 5, 6, 10-14, 16, 19 and 49 have also been rejected under 35 U.S.C. 102(e) as being anticipated by Kagan (US 2005/0240279 A1).

Disclosed embodiments will be discussed without limitation of the claims. As shown in Applicant's Figure 2, a restrictive device is implanted by a physician in the upper part of the stomach. The restrictive device can be a two-piece device including an anchoring cuff 217 and a removable restrictive member 224 with an aperture 218 through which food transits. The removable member can have an exterior perimeter sized to contact inner walls of the stomach. For example, the restrictive member can have an external diameter between about 7 and about 20 centimeters. The anchoring cuff is fixedly coupled to the stomach, and the restrictive membrane is removably coupled to the anchoring cuff. The restrictive member can be planar in shape.

First, the restrictive device divides the stomach into two chambers: an upper chamber, near the esophagus, and a lower chamber. Dividing the interior of the stomach in this manner restricts the volume of the upper stomach available to hold ingested food. Thus, the size of the stomach immediately available for food is effectively reduced in a minimally invasive manner. Preferably, the upper stomach chamber has a volume between about 30 and about 100 cubic centimeters (cc).

The positioning of the device in the upper stomach is advantageous in many ways. Firstly, the location in the upper stomach is safer as compared to devices positioned in the esophagus or gastro esophageal junction (GEJ). Interfering with GEJ valve function as does an esophageal device, can cause serious safety concerns. Being anchored in the upper stomach as opposed to in the GEJ prevents interference with normal gastro esophageal functions.

Further, the width of the restrictive member (between about 7-20cm to match the stomach size and depending on the size of the stomach pouch desired) allows it to sit in the stomach while placing minimal tension on the stomach.

Additionally, the removable restrictive member permits the physician to change the size of the opening of the restrictive member in a minimally invasive manner by replacing the member with another member having an aperture of a different size and/or shape.

Also, the planar shape of the membrane is advantageous in that one can obtain a small volume above the member with the device mounted to the stomach below the GEJ. For example, anchoring higher in the upper stomach reduces the volume of the stomach chamber above the membrane while anchoring lower in the stomach increases that volume of the stomach chamber.

For example, an esophageal valve type device or any hanging valve/pouch device would not function adequately in the stomach as does Applicant's device. In order to create an upper stomach chamber between 30-100cc as is preferred by the Applicant, a device that itself had a significant length and resultant volume would need to be anchored high within the GEJ. Thus, Applicant's planar shape allows it to be placed anywhere within the stomach to fully control the size of the desired chamber, even to a small volume. A pouch, valve, or stoma on the other hand, also has additional volume to consider when creating the stomach chamber.

Stack describes a device for inducing weight loss that includes a tubular prosthesis positionable at the gastro-esophageal junction region. The prosthesis is placed such that an

opening at its proximal end receives masticated food from the esophagus, and such that the masticated food passes through the pouch and into the stomach via an opening in its distal end.

As shown in Stack's Figure 2, the device includes a pouch 12 that is anchored in the gastroesophageal region and extends into the upper stomach. The pouch includes a proximal opening 14 that is positionable at the gastroesophageal junction region and a distal opening 16 that opens into the interior of the stomach.

Stack does not describe a substantially planar restrictive member for implantation into a stomach of an animal having an exterior width between 7-20cm as does the Applicant. Though Stack does not state what the diameter of anchor of the device is, it would be smaller as it is anchored in the gastroesophageal junction (GEJ).

Applicant's independent claim 1 has been amended to recite a substantially planar restrictive member configured for implantation into a stomach of an animal, and the restrictive member having an outer width between 7 and 20 centimeters. The claim has been further amended to recite the anchor having an exterior perimeter adapted to contact inner walls of the stomach. As stated, these limitations are not described by Stack's esophageal device.

Thus, claim 1 and any claim dependent on the same is allowable over Stack for at least these reasons.

Claims 1, 2, 5, 6, 10-14, 16, 19 and 49 have also been rejected under 35 U.S.C. 102(e) as being anticipated by Kagan.

Kagan describes an apparatus for treatment of morbid obesity. Kagan's device can be seen in Kagan's Figure 1. The first component is an artificial stoma 100 located in the stomach or lower esophagus that reduces the flow of food into the stomach. The stoma can be anchored to the esophageal or stomach wall using sutures, staples, clips, or other anchoring mechanisms. It can also be used in conjunction with gastric suturing, stapling, or banding to create a narrow passage for installation of the stoma and for reduction of gastric volume, as seen in Figure 1. The artificial stoma can include a fabric cuff on the outer circumference to facilitate in-growth of tissue to secure the device. Alternatively, the stoma device can include a separate anchoring device that is in the form of an anchoring ring like the one shown in Figures 2A-2B.

Kagan does not describe substantially planar restrictive member as does the Applicant. The shape of Kagan's stoma can be seen in Figures 7A-7B.

Further, Kagan does not describe the restrictive member having an outer width between 7 and 20 centimeters. In the embodiments where Kagan's stoma and anchoring ring contact the walls of the stomach, the walls of the stomach are pulled to create a narrowing. The stoma itself is not sized to sit in the stomach as is Applicant's planar restrictive member and anchor. As stated, the width of Applicant's planar restrictive member between about 7-20cm matches the stomach size and allows it to sit in the stomach while placing minimal tension on the stomach.

Therefore, Kagan does not teach all of the limitations of amended claim 1, and claim 1 and any dependent claims are allowable over Kagan.

103(a) Rejections

Dependent claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack.

Stack has been discussed with regard to the 102(e) rejection of independent claim 1 on which claims 3-4 are dependent. Because Stack does not suggest all of the limitations of independent claim 1 as discussed above, dependent claims 3-4 are allowable for at least these reasons.

Supplemental Information Disclosure Statements

A Supplemental Information Disclosure Statement was filed on May 16, 2007, and a Supplemental Information Disclosure Statement is being filed concurrently herewith. Entry of the Supplemental Information Disclosure Statements is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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